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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/070,434	07/22/2002	Shigeo Takada	P22129	9207

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EXAMINER	
GOLLAMUDI, SHARMILA S	

ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 10/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/070,434	TAKADA ET AL.	
	Examiner	Art Unit	
	Sharmila S. Gollamudi	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 March 2002*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt of Preliminary Amendment received March 19, 2002 and the Information Disclosure Statements of September 20, 2002 and April 5, 2004 is acknowledged. Claims **1-20** are pending in this application.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 9/20/02 and 4/5/04 was filed have been considered.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 6 recites "acidshavingg", which is vague and indefinite. The meaning of this phrase is unclear. Clarification is requested.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-20 are rejected under 35 U.S.C. 102(b) as being anticipated by JP 10-130153 to Youichirou et al (based on entire document).

JP discloses an anti-malignant tumor agent that comprises a cyclic and straight chain mixed with poly L-lactic acid having a 3-19 degree condensation as the main component. The agent has the instant cyclic lactic acid oligomer of instant formula. See paragraph 0017. The agent is obtained by dehydrating and condensing L-lactic acid in a nitrogen gas atmosphere by reduction in pressure and heating by stages to give a reaction solution, drying the soluble components of the reaction solution with ethanol and methanol under reduced pressure, carrying out reverse phase ODS column chromatography, eluting the adsorbed substance with 25-50% of acetonitrile aqueous solution at a pH of 2, and collecting a fraction prepared by elution with 100% acetonitrile at a pH of 2. See abstract and examples in computer translation. The agent is mixed with other carriers to provide an oral composition (liquid, capsules, or powder). see paragraph 0012 and paragraph 0019.

Note that the preamble of the instant claims , i.e. an agent for enhancing stamina and an agent for promoting glycogen accumulation, is not given patentable weight since it recites the intended purpose of the agent and the body of the claim does not depend on the preamble for completeness. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

Additionally, the intended use limitation in the instant claims, i.e. which is used to recover from fatigue, is not given patentable weight since the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art, and in instant case it does not.

Claims 1-3, 5-13, and 15-20 are rejected under 35 U.S.C. 102(b) as being anticipated by JP 07233061 to Youichirou et al.

Youchirou et al disclose production of orally administering agent having an action for suppressing proliferation of malignant tumor cells. The method consists of heating L-lactic acid, while aerating nitrogen gas, an inert gas, at ordinary pressure to under reduced pressure to produce a reaction liquid. This reaction liquid contains a mixture of L-lactic acid straight chain condensate having 3-25 degree of condensation and L-lactic acid cyclic condensate having 2-15 degree of condensation. The reaction liquid is suspended in ethanol and divided into a soluble component and an insoluble component, then subjected to a neutralization treatment. The agent is then mixed with a food additive to facilitate intake. See abstract.

Note that the preamble of the instant claims, i.e. an agent for enhancing stamina and an agent for promoting glycogen accumulation, is not given patentable weight since it recites the intended purpose of the agent and the body of the claim does not depend on the preamble for completeness. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

Additionally, the intended use limitation in the instant claims, i.e. which is used to recover from fatigue, is not given patentable weight since the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art, and in instant case it does not.

Lastly, it should be noted that instant claims 6-8 and 16-18 are product-by-process claims. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the

prior product was made by a different process. In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). See MPEP 2113.

Claims 1-20 are rejected under 35 U.S.C. 102(b) as being anticipated by JP 09227388 to Naganushi et al.

Naganushi et al disclose an anti-malignant tumor agent that comprises a mixture of L-lactic acid oligomers bearing cyclic and straight chains as a main component, which possesses a condensation degree of 9-19. The agent has the instant cyclic lactic acid oligomer of instant formula. See paragraph 0018. The agent is obtained by condensing L-lactic acid by means of dehydration under stepwise reduced pressures at elevated temperature in a nitrogen atmosphere, followed by drying the soluble components of the reaction solution with ethanol and methanol under reduced pressure, carrying out reverse phase ODS column chromatography, eluting the adsorbed substance with 25-50% of acetonitrile aqueous solution at a pH of 2, and collecting a fraction prepared by elution with 100% acetonitrile at a pH of 2. see abstract.

Note that the preamble of the instant claims , i.e. an agent for enhancing stamina and an agent for promoting glycogen accumulation, is not given patentable weight since it recites the intended purpose of the agent and the body of the claim does not depend on the preamble for completeness. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

Additionally, the intended use limitation in the instant claims, i.e. which is used to recover from fatigue, is not given patentable weight since the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art, and in instant case it does not.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-21 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of copending Application No. 10/483254, 10/466541, 10/451786, 10/181421, 10/088523, 10/130300. Although the conflicting claims are not identical, they are not patentably distinct from each other because since all the listed co-pending application are directed to common subject matter.

Instant claims are directed to an agent for enhancing stamina which comprises , as an active ingredient , a mixture of cyclic and/or straight chain poly lactic acids having a condensation degree of 3 to 20.

'300 is directed to an agent for enhancing which comprises , as an active ingredient , a mixture of cyclic and/or straight chain poly lactic acids having a condensation degree of 3 to 19 .

'523 is directed to an appetite suppressing agent which comprises, as an active ingredient, a mixture of cyclic and/or straight chain poly lactic acids having a condensation degree of 3 to 19.

'254 is directed to antitumor agent which comprises a mixture of polylactic acids which contains cyclic polylactic acids having a condensation degree ranging from 3 to 20 as main component.

'541 is directed to an antistress agent which comprises a mixture of cyclic and/or straight chain poly lactic acids having a condensation degree of 3 to 19.

'786 is directed to an antiallergic agent which comprises a mixture of cyclic and/or straight chain poly lactic acids having a condensation degree of 3 to 19.

'421 is directed to an agent for preventing the implantation of cancer cells which comprises, as an active ingredient, a mixture of cyclic and/or straight chain poly lactic acids having a condensation degree of 3 to 19.

First, is pointed out that the preamble and the intended use recitations of the instant claims and those of the above co-pending product claims are not afforded patentable weight. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See In re Hirao, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and Kropa v. Robie, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

Additionally, the recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making,

the intended use must result in a manipulative difference as compared to the prior art. See In re Casey, 152 USPQ 235 (CCPA 1967) and In re Otto, 136 USPQ 458, 459 (CCPA 1963).

Furthermore, regarding the product by process dependent claims of the instant application and the co-pending applications, it is pointed even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. in re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). See MPEP 2113.

Thus, since the instant claims and the above co-pending application claims, all recite the same agent, i.e. a mixture of cyclic and/or straight chain poly lactic acids having a condensation degree of 3 to 19, and although the agents have different intended uses, the instant claims are an obvious over each other since the same compound is being claimed.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

None of the claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is 571-272-0614. The examiner can normally be reached on M-F (8:00-5:30), alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sharmila S. Gollamudi
Examiner
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